

## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

### General Information

Trade Name	HD Guide Catheter
Common Name	Percutaneous Catheter
Classification	Percutaneous Catheter, 21CFR 870.1250 – Class II

Submitter	Concentric® Medical, Inc. 301 E. Evelyn Avenue Mountain View, CA 94041 Tel 650-938-2100 Fax 650-938-2700
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MAY - 6 2009

Contact	Laraine Pangelina Director, Regulatory Affairs
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### Intended Use

The HD Guide Catheter is indicated for use in facilitating the insertion and guidance of an occlusion catheter, infusion catheter or other appropriate microcatheter into a selected blood vessel in the peripheral, coronary or neuro vascular systems. It may also be used as a diagnostic angiographic catheter.

### Predicate Device

HD Guide Catheter, K080583

### Device Description

The HD Guide Catheter consists of a single lumen, braided, variable stiffness shaft with a radiopaque marker on the distal end and a luer hub on the proximal end. The catheter shaft has a hydrophilic coating to reduce friction during use. A rotating hemostatic valve with side-arm adapter is provided with each catheter.

### Materials

All materials used in the manufacture of the HD Guide Catheter are suitable for the intended use of the device and have been used in numerous previously cleared products.

### Testing Summary

The results of verification and validation conducted on the HD Guide Catheter demonstrate that it performs as designed, is suitable for its intended use and is substantially equivalent to the predicate device.

### Summary of Substantial Equivalence

The HD Guide Catheter is substantially equivalent to the predicate device with regard to device design, intended use, patient population and anatomical site. Any differences in technological characteristics between the HD Guide Catheter and the predicate device do not raise any new issues of safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY - 6 2009

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Concentric Medical  
c/o Ms. Laraine Pangalina  
Director, Regulatory Affairs  
301 East Evelyn Avenue  
Mountain View, CA 94041

Re: K090335

Trade/Device Name: Concentric HD Guide Catheter  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II  
Product Code: DQY  
Dated: April 16, 2009  
Received: April 20, 2009

Dear Ms. Pangalina:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

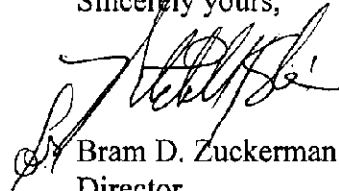
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device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Bram D. Zuckerman', is written over the typed name.

Bram D. Zuckerman, M.D.  
Director

Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**INDICATIONS FOR USE**

510(k) Number (if known): This application

Device Name: HD Guide Catheter

Indications for Use: The HD Guide Catheter is indicated for use in facilitating the insertion and guidance of an occlusion catheter, infusion catheter or other appropriate microcatheter into a selected blood vessel in the peripheral, coronary or neuro vascular systems. It may also be used as a diagnostic angiographic catheter.

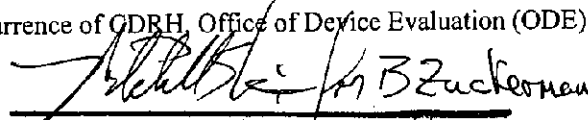
Prescription Use X  
(Per 21 CFR 801.109)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of GDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off) 5/5/09

Division of Cardiovascular Devices

510(k) Number K090335